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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/713,790	11/12/2003	Gerald B. Pier	B0801.70255US01	5867

23628 7590 03/06/2009

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EXAMINER	
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ART UNIT	PAPER NUMBER
1645	

MAIL DATE	DELIVERY MODE
03/06/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/713,790	PIER ET AL.	
	Examiner	Art Unit	
	S. Devi, Ph.D.	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 December 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-25,42 and 86-98* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-25,42 and 86-98* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 November 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *010709*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Request for Continued Examination

1) A request for continued examination under 37 C.F.R 1.114, including the fee set forth in 37 C.F.R 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 C.F.R 1.114, and the fee set forth in 37 C.F.R 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 C.F.R 1.114. Applicants' submission filed on 12/17/08 has been entered.

Applicants' Amendment

2) Acknowledgment is made of Applicants' amendment filed 12/17/08 in response to the final Office Action mailed 06/17/08.

Status of Claim(s)

3) Claims 1, 2, 7-11, 14-16, 20, 21, 25, 42, 86, 87 and 95 have been amended via the amendment filed 12/17/08.

Claims 1, 2, 4-25, 42 and 86-98 are pending and are under examination.

Prior Citation of Title 35 Sections

4) The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

Prior Citation of References

5) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

Rejection(s) Withdrawn

6) The rejection of claim 42 made in paragraph 25(d) of the Office Action mailed 05/15/07 and maintained in paragraph 20 of the Office Action mailed 06/17/08 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

7) The rejection of claims 1, 2, 4-25, 42 and 86-98 made in paragraph 21 of the Office Action mailed 06/17/08 under the judicially created doctrine of obviousness-type double

patenting over claim 1 of US patent 7,252,828 (Applicants' IDS) ('828) in view of Fattom *et al.* (*Infect. Immun.* 66: 4588-4592, 1998) and the rejection of 18 under the judicially created doctrine of obviousness-type double patenting over claims 9-11 of US patent 7,252,828 in view of Fattom *et al.* (*Infect. Immun.* 66: 4588-4592, 1998), is withdrawn. A new rejection is set forth below. Applicants' arguments to the extent still applicable are addressed below.

The Applicants' statement that the glucosamine residues of the '828 patent's polysaccharide may be acetate-substituted, succinate-substituted, and/*or unsubstituted* has been noted. See the fourth full paragraph on page 11 of Applicants' amendment/response filed 12/17/08. Thus, the polysaccharide disclosed by the '828 patent encompasses the PS/A polysaccharide antigen comprising acetate-**unsubstituted** and/or succinate-**unsubstituted** glucosamine residues, i.e., 0% acetate substitution.

Applicants assert that the polymers of the rejected claims are composed of 'glucosamine residues only', and that these glucosamine residues are either *unsubstituted* or substituted with acetate, provided that less than 40% or less than 50% of glucosamine residues are acetate substituted. Applicants submit that the claimed polymers 'do not include glucose, galactose' or succinate substituted glucosamine residues. See last full paragraph on page 11 of Applicants' amendment/response filed 12/17/08. Applicants contend that the polymers of the rejected claims differ from the description of the asserted claims in the lack of glucose, galactose and succinate-substituted glucosamine residues, and the lack of acetate substitution of glucosamine residues. Applicants state that the Office incorrectly concludes that the only difference between Applicants' polymers and the ones disclosed by the '828 patent is the level of acetate substitution.

Applicants' arguments have been carefully considered, but are not persuasive. Contrary to Applicants' assertion, the product claimed, for example, in claim 86 is not drawn to a 100% pure polysaccharide consisting of a beta-1,6-glucosamine polymer, wherein less than 50% of glucosamine amino groups are substituted with acetate, but to an 'isolated' polysaccharide 'comprising' a beta-1,6-glucosamine polymer, wherein less than 50% of glucosamine amino groups are substituted with acetate. The transitional limitations 'comprising', 'consisting essentially of' and 'consisting of' define the scope of a claim with respect to what unrecited additional components or steps, if any, are excluded from the scope of the claim. The transitional

term 'comprising', which is synonymous with 'including', 'containing' or 'characterized by' is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. *Moleculon Research Corp. v. CBS, Inc., 793 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1986)*; *In re Baxter, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981)*; and *Ex parte Davis, 80 USPQ 448, 450 (Bd. App. 1948)* ('comprising' leaves 'the claim open for the inclusion of unspecified ingredients even in major amounts'). An 'isolated' polysaccharide or polymer 'comprises' impurities and other antigenic and non-antigenic elements therein, and therefore it does not exclude the presence of glucose, galactose etc. Similarly, the product claimed in claim 1 is not drawn to a composition consisting of 100% pure beta-1,6-glucosamine polymers, wherein less than 40% of glucosamine amino groups in the polymers are substituted with acetate, but to a composition 'comprising isolated' beta-1,6-glucosamine polymers, wherein less than 40% of glucosamine amino groups are substituted with acetate. The 'isolated' polymers recited in claim 1 comprises impurities and other antigenic and non-antigenic elements therein, and therefore these polymers do not exclude the presence of glucose, galactose etc. Therefore, the PS/A polysaccharide antigen of the '828 patent comprising acetate-**unsubstituted** and/or succinate-**unsubstituted** glucosamine residues, i.e., glucosamine residues with 0% acetate substitution, and a composition comprising the same in a pharmaceutically acceptable carrier anticipate the instantly claimed products. See the art rejection(s) set forth below.

8) The rejection of claims 1, 2, 4-25, 42 and 86-98 made in paragraph 28 of the Office Action mailed 06/17/08 under 35 U.S.C. 103(a) as being obvious over US patent 7,252,828 (Applicants' IDS) ('828) in view of Fattom *et al.* (*Infect. Immun.* 66: 4588-4592, 1998), is withdrawn. A new rejection is set forth below. Applicants' arguments to the extent still applicable are addressed in the paragraph immediately above.

9) The rejection of claims 1 and 2 made in paragraph 23(a) of the Office Action mailed 06/17/08 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claims.

10) The rejection of claim 87 made in paragraph 23(b) of the Office Action mailed 06/17/08 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

11) The rejection of claims 4-20, 90 and 91 made in paragraph 23(c) of the Office Action mailed 06/17/08 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the base claim.

12) The rejection of claims 1, 2, 4-16, 18-24, 42 and 86-97 made in paragraph 25 of the Office Action mailed 06/17/08 under 35 U.S.C § 102(b) as being anticipated by McKenney *et al.* (*Infect. Immun.* 66: 4711-4720, October 1998 - Applicants' IDS) (McKenney *et al.*, 1998), is withdrawn upon further consideration and in light of Applicants' arguments.

13) The rejection of claims 17, 25 and 98 made in paragraph 27 of the Office Action mailed 06/17/08 under 35 U.S.C § 103(a) as being unpatentable over McKenney *et al.* (*Infect. Immun.* 66: 4711-4720, October 1998 - Applicants' IDS) (McKenney *et al.*, 1998) as applied to claims 15, 1, 22 and 21 above, and further in view of Pier *et al.* (US 20020119166 – Applicants' IDS), is withdrawn upon further consideration and in light of Applicants' arguments.

Rejection(s) under 35 U.S.C § 112, First Paragraph (New Matter)

14) The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

15) Claims 1, 2, 21 and the dependent claims 4-20, 22-25, 42 and 98 are rejected under 35 U.S.C § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The amendment introduced to claim 1 replaces the previous limitation 'an isolated polysaccharide comprising a beta-l,6-glucosamine polymer, wherein less than 40% of glucosamine amino groups in the composition are substituted …. wherein the isolated polysaccharide has a structure' with the new limitation 'isolated beta-l,6-glucosamine polymers, wherein less than 40% of glucosamine amino groups in the isolated polymers are substituted … wherein each of the isolated polymers has a structure'. The now recited 'isolated beta-l,6-glucosamine polymers' are not required to be comprised in an isolated polysaccharide, whereas

the previously recited 'a beta-1,6-glucosamine polymer' was required to be comprised within the previously recited 'an isolated polysaccharide'. Similar amendments have been made to the independent claims 2 and 21. Additionally, in claim 2, as amended currently, the recited isolated beta-l,6-glucosamine polymers are required to be conjugated to pleural 'carrier compounds' as opposed to the previously recited 'a carrier compound'. In the dependent claims 8-10, 15 and 16, as amended currently, the previously recited 'the isolated polysaccharide' is replaced with 'each of the isolated polymers'. Claim 25 has been amended wherein the carrier polysaccharide compound is now required not to be an N-acetyl beta-l,6-glucosamine 'polymer' as opposed to the previously recited 'N-acetyl beta-l,6-glucosamine'. Claims 7, 11, 14, 20 and 42 have also been amended. Applicants do not point to specific parts of the specification that provide support for the newly added limitations and/or for the current scope of the claims. Therefore, the above-identified new limitation in the instant claim(s) is considered to be new matter. *In re Rasmussen*, 650 F2d 1212 (CCPA, 1981). New matter includes not only the addition of wholly unsupported subject matter but also, adding specific percentages or compounds after 608.04(c).

Applicants are invited to point to specific line and page numbers of the specification, as originally filed, that provide descriptive support for the limitation(s) identified above, or alternatively, remove the new matter from the claims. Applicants should specifically point out the support for any amendments made to the disclosure. See MPEP 714.02 and 2163.06.

Rejection(s) under 35 U.S.C § 112, First Paragraph (Written Description)

16) Claims 21, 86 and 97 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Claim 21 is drawn to a composition comprising isolated, at least 800 Daltons beta-1,6-glucosamine polymers wherein less than 40% of glucosamine amino groups are substituted with acetate, wherein each of the isolated polymers consists of the structure recited therein wherein each of X1, X2, X3, X4, X5 and X6 as well as each of Y1, Y2 and Y3 is carrier compound or a linker joined to a carrier compound. Claim 86 is drawn to an isolated polysaccharide comprising a beta-1,6-glucosamine polymer, wherein less than 50% of glucosamine amino groups are

substituted with acetate and wherein the isolated polysaccharide has the structure recited therein, wherein each of X1, X2, X3, X4, X5 and X6 as well as each of Y1, Y2 and Y3 is a carrier compound or a linker joined to a carrier compound. The scope of the claims encompass isolated beta-1,6-glucosamine polymeric structures as recited wherein all of X1, X2, X3, X4, X5 and X6 and all of Y1, Y2 and Y3 are carrier compounds such as full-length proteins, peptides, nucleic acids, lipids, polysaccharides, toxins, other polymers etc. (see page 18 of Applicants' specification) and/or linkers joined to the carrier compounds. Thus, the overall structure of the recited polymers or the polysaccharide wherein all of X1, X2, X3, X4, X5 and X6 and all of Y1, Y2 and Y3 are carrier compounds and/or linkers joined to the carrier compounds is expected to be modified or altered considerably compared to the native PNAG or PS/A by the presence of nine carrier compounds and/or linkers joined to the carrier compounds. The carrier compounds or the linkers joined thereto encompass different, structurally divergent carrier compounds or linkers on each polymer. The recited polymeric structures are linked to one or more carrier compounds, or linkers joined to one or more carrier compounds, at multiple sites of the polymers. Such a product claimed in the instant claims is *required* to serve as or intended to be used as a 'vaccine' capable of inducing antibodies to native beta-1,6-glucosamine polymers or to a polysaccharide comprising a native beta-1,6-glucosamine polymer. The isolated polysaccharide of the dependent claim 97 is formulated as 'a vaccine'. The specification intends vaccine (prophylactic) applications for the product claimed in claim 21. The objective of the instant invention is to use the claimed isolated polymer or polysaccharide composition as a vaccine for active immunization of humans and animals to prevent staphylococcal infections, including *S. aureus* and *S. epidermidis* infections. See pages 26-28 of the instant specification.

The *Written Description Guidelines* state:

> There is an inverse correlation between the level of predictability in the art and the amount of disclosure necessary to satisfy the written description requirement. For example, if there is a well-established correlation between the structure and function in the art, one skilled in the art will be able to reasonably predict the complete structure of the claimed invention from its function.

A review of the instant specification indicates that Applicants were in possession of pure dPNAG species with tetanus toxoid or diphtheria toxoid carrier protein conjugated thereto. See Examples 4-6. However, Applicants were not in possession of isolated dPNAG polymer or polysaccharide species that are extensively modified by containing nine different carrier

compounds and/or linkers joined to the carrier compounds at X1, X2, X3, X4, X5 and X6 and Y1, Y2 and Y3, wherein the product *concurrently* retained the ability to serve as a 'vaccine', i.e., the capacity to elicit a prophylactic immune response to native beta-1,6-glucosamine polysaccharide as it exists naturally on pathogens, for example, *Staphylococcus aureus* and *Staphylococcus epidermidis*. While one of skill in the art would be able to produce the isolated polymers or polysaccharide having carrier compounds and/or linkers joined to the carrier compounds at X1, X2, X3, X4, X5 and X6 and Y1, Y2 and Y3 of the recited structure, there is no predictability the resultant heavily derivatized polymer or polysaccharide product would retain acceptable solubility and retain the ability to elicit an immune response directed to the native beta-1,6-glucosamine polymers or a polysaccharide comprising a native beta-1,6-glucosamine polymer. This is important because the art recognizes that specific physical-chemical attributes of polysaccharide-protein conjugate vaccines influence immunogenicity and protective efficacy. See third full paragraph on page 2191 of Wessels *et al.* (*Infect. Immun.* 66: 2186-2192, 1998). The modification of polysaccharides or modification of crucially important epitopes including immunodominant conformational epitopes on the polysaccharides leads to products that induce antibodies not capable of recognizing the native polysaccharides. The extent of cross-linking between the polysaccharide and the protein components in a given conjugate influences the immunogenicity of the conjugate. See the sentence bridging the two columns on page 2190 of Wessels *et al.* For example, highly cross-linked conjugate vaccines evoke antibodies having reduced functional activity due to *the alteration* of the polysaccharide epitope; and the antibodies induced by such conjugate vaccines bind less avidly to the native polysaccharide. See paragraph bridging pages 2189 and 2190 of Wessels *et al.* Highly cross-linked conjugate vaccines have been shown to produce polysaccharide-specific antibodies directed to nonprotective epitopes. Wessels *et al.* taught that antibodies evoked by highly cross-linked conjugate vaccines recognize a novel epitope in modified bacterial capsular polysaccharide, whether or not coupled to a protein, 'that is not present' in the untreated (i.e., unmodified or native) bacterial capsular polysaccharide. See the last sentence in the paragraph bridging pages 2189 and 2190 of Wessels *et al.* The polysaccharide-protein conjugate vaccines constructed by linking the polysaccharide to the carrier protein *at multiple sites* along the polysaccharide chain are known to have several effects including close apposition of

polysaccharide and protein epitopes at several sites in the conjugate, constraint of polysaccharide flexibility, and creation of lattice-like structures linking several molecules of each vaccine component, each influencing conjugate's immunogenicity 'by altering epitopes of one of both components or by modifying the interaction between antigen-specific B and T cells'. See third full paragraph under 'Discussion' of Wessels *et al*. The highly cross-linked conjugates elicit antibodies that recognize an epitope formed by extensively oxidized (i.e., modified) bacterial capsular polysaccharide, but not an epitope present on the native unmodified bacterial capsular polysaccharide. See last sentence in the second full paragraph on page 2191 of Wessels *et al*. The extensive modification of the bacterial capsular polysaccharide appeared to 'distort the epitope of the polysaccharide' in highly cross-linked conjugate vaccines. See third full paragraph on page 2191 of Wessels *et al*. Given the art-recognized unpredictability of retaining the protective epitopes within a modified bacterial polysaccharide, one of skill in the art cannot ascertain from the instant disclosure, which precise structure or epitope(s) within the isolated dPNAG polymer or polysaccharide species containing carrier compounds and/or linker-containing carrier compounds at all of X1, X2, X3, X4, X5 and X6 and/or all of Y1, Y2 and Y3 provides for the required function, i.e., capacity to serve as a vaccine by inducing an optimal immune response that recognizes the native beta-1,6-glucosamine polymers or a polysaccharide comprising a beta-1,6-glucosamine polymer. *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1568 (Fed. Cir. 1997), cert. denied, 523 U.S. 1089, 118 S. Ct. 1548 (1980), holds that an adequate written description requires 'not a mere wish or plan for obtaining the claimed ……. invention.' *Eli Lilly*, 119 F.3d at 1566. *Vas-Cath Inc. V. Mathukar, 19 USPQ2d 1111* states that Applicant 'must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention, is for purposes of the 'written description' inquiry, whatever is now claimed.' See page 1117. The specification does not 'clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.' See page 1116 of *Vas-Cath Inc. V. Mathukar, 19 USPQ2d 1111*. Applicants should also note that *Vas-Cath Inc. V. Mathukar, 19 USPQ2d 1111* makes clear that the written description provision of 35 U.S.C § 112, first paragraph, is severable from its enablement provision. See page 1115. Regardless of the complexity or simplicity of making the product, conception cannot be

achieved until reduction to practice has occurred. Adequate written description requires more than a mere statement that it is a part of the invention. See *Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993)* and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016*. The claims are viewed as not meeting the written description provision of 35 U.S.C § 112, first paragraph.

Double Patenting Rejection(s)

17) Claims 1, 2, 4-6, 8-17, 19-25, 86-94 and 96-98 are rejected under the judicially created doctrine of obviousness-type double patenting over claim 1 of the US patent 7,252,828 (of record) ('828). Claims 18, 42 and 95 are rejected under the judicially created doctrine of obviousness-type double patenting over claim 9 of the US patent 7,252,828 (of record) ('828).

Instant claims are directed to an invention not patentably distinct from the above-identified claims of the commonly assigned '828 patent. Specifically, the product of claims 1 and 9 of the above-identified patent falls within the scope of the above-identified instant claims. The PS/A polysaccharide antigen claimed in claim 1 and contained in the pharmaceutical composition of claim 9 of the '828 patent is not required to have acetate substituted glucosamine residues and therefore falls within the scope of the instant claims. The portion of the disclosure from the '828 patent that provides support for the isolated PS/A polysaccharide composition also does not require the PS/A to be acetate-substituted, and therefore the PS/A has 0% acetate substitution, i.e., less than 40%, less than 50%, or less than 35% acetate substitution. See lines 4-19 of column 3. The portions of the disclosure from the '828 patent that provide support for the isolated polymer composition having a molecular weight of >100,000 Daltons and being greater than 92% pure as claimed, do not exclude, but expressly include an isolated sterile beta-1,6-glucosamine polymer composition as claimed in claims 1 and 9 of the '828 patent. Applicants have acknowledged that the '828 patent's PS/A polysaccharide antigen comprising beta-1,6-glucosamine polymers comprises acetate-**unsubstituted** and/or succinate-**unsubstituted** glucosamine residues, i.e., 0% acetate substituted glucosamine residues. See paragraph 7 *supra*. Thus, the structure of the prior art polymer is identical to the acetate-unsubstituted polymer encompassed within the scope of instant claims. Furthermore, the portions of the disclosure from the '828 patent that provide support for the isolated PS/A polysaccharide composition

taught the integer n to be 3-6, 3-20, or equal to or grater than 490; the molecular weight to be between 100,000 and 5,000,000; the carrier compound linked directly or via a linker to the PS/A to be a peptide, protein, or other polysaccharide; and the composition to be sterile. See claims 1, 4-6 and 9; the structure disclosed in column 3; last full paragraph in column 3; fourth full paragraph in column 4; and last paragraph in column 6. The portions of the disclosure from the '828 patent that provide support for the isolated PS/A polysaccharide composition taught the composition to be sterile, formulated as a vaccine or a pharmaceutical or therapeutic composition comprising a pharmaceutically acceptable carrier. See first full paragraph in column 24; third full paragraph in column 3; and second, fourth and fifth full paragraphs in column 23. The portion of the disclosure from the '828 patent that provides support for the isolated PS/A polysaccharide composition taught that the PS/A polymers are conjugated to carrier compounds such as peptide, protein, or other polysaccharide polymer carriers either directly or via a linker. See second full paragraph in column 14.

Rejection(s) under 35 U.S.C § 112, Second Paragraph

18) The following is a quotation of the second paragraph of 35 U.S.C. § 112:

> The specification shall conclude one or more claims particularly pointing out and distinctly claiming the subject matter which the Applicant regards as his/her invention.

19) Claims 22-25, 42 and 86-97 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

(a) Claim 42 is vague in the limitation: 'stimulate an immune response in a subject', because it is unclear what this immune response is directed against. Is the immune response stimulated against a pathogen, or is this an immune-stimulating adjuvant response induced by the recited polymers? Clarification is requested.

(b) In line 3 of claim 86 and line 2 of claim 87, for the purpose of distinctly claiming the subject matter, it is suggested that Applicants replace the limitation 'a structure' with the limitation --the structure--.

(c) Claim 22 lacks proper antecedent basis in the limitation 'a carrier compound' (see line 2) and is inconsistent with the claim language --the carrier compound-- used in line 2 of claims 23 and 24.

(d) Claim 22 is indefinite and confusing in the limitation: wherein only one of the carrier compound or the linker joined to a carrier compound 'is conjugated to the structure'. Claim 22 depends from claim 21, wherein 'the structure' is the chemical structure that is depicted therein, wherein a carrier compound or a linker joined to a carrier compound is a part of the whole structure, the carrier compound or the linker being confined to X1, X2, X3, X4, X5, X6, Y1, Y2 and/or Y3. In other words, in the base claim 21, X1, X2, X3, X4, X5, X6, Y1, Y2 and/or Y3 **is** a carrier compound or a linker as recited therein. It is unclear how, in the dependent claim 22, one of the carrier compounds or the linker joined to a carrier compound can be 'conjugated to the structure'. Note that 'the structure' includes areas other than X1, X2, X3, X4, X5, X6, Y1, Y2 and Y3. Is one of the carrier compound or the linker joined to a carrier compound 'conjugated to the structure' at a point other than X1, X2, X3, X4, X5, X6, Y1, Y2 and Y3? A carrier compound or a linker being present at X1, X2, X3, X4, X5, X6, Y1, Y2 or Y3 is different in scope from a carrier compound or a linker that is conjugated to the recited whole structure.

(e) Analogous rejection and criticism apply to dependent claims 23 and 24.

(f) Claims 87-97, which depend from claim 86, and claim 25, which depends from claim 22, are also rejected as being indefinite because of the indefiniteness identified above in the base claim.

Rejection(s) under 35 U.S.C § 102

20) The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> **(e)** the invention was described in-
> **(2)** a patent granted on an application for patent by another filed in the United States before the invention by the Applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

21) Claims 1, 2, 4-6, 8-25, 42 and 86-98 are rejected under 35 U.S.C. 102(e)(2) as being anticipated by Pier *et al.* (US patent 7,252,828, of record) ('828).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention 'by another', or by an appropriate showing under 37 CFR 1.131.

The transitional limitation 'comprising' similar to the limitations 'having', 'including', containing', or 'characterized by' represents open-ended claim language and therefore, does not exclude additional, unrecited elements. See MPEP 2111.03 [R-1]. See *Moleculon Research Corp. v. CBS, Inc., 793 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1986)*; *In re Baxter, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981)*; *Ex parte Davis, 80 USPQ 448, 450 (Bd. App. 1948)* ('comprising' leaves 'the claim open for the inclusion of unspecified ingredients even in major amounts'). Therefore, the limitation 'comprising' in the instant claim(s) allows additional elements such as glucose and galactose to be present with the claimed isolated product.

Pier *et al.* ('828) disclosed isolated PS/A polysaccharides having a molecular weight of >100,000 Daltons and being greater than 92% pure, and a composition comprising the same. The prior art product does not exclude, but expressly encompasses isolated sterile beta-1,6-glucosamine polymers and a composition comprising the same. The product claimed in claim 1 of Pier *et al.* ('828) and the one disclosed in lines 4-19 of column 3 of Pier *et al.* ('828) are not required to be acetate substituted and therefore have 0% acetate substitution, i.e., less than 40%, less than 50%, or less than 35% acetate substitution. Applicants have acknowledged that the '828 patent's PS/A polysaccharide antigen comprising beta-1,6-glucosamine polymers comprises acetate-**unsubstituted** and/or succinate-**unsubstituted** glucosamine residues, i.e., 0% acetate-substituted glucosamine residues. See paragraph 7 *supra*. Thus, the structure of the prior art polymer is identical to the acetate-unsubstituted polymer encompassed within the scope of instant claims. The integer n is 3-6, 3-20, or equal to or grater than 490, and the molecular weight is 150,000 or 250,000. The structure of the polymer is identical to the instantly recited

unsubstituted polymer, with 0% of glucosamine amino groups in the polysaccharide substituted with acetate. See claims 1, 4-6 and 9; the structure disclosed in column 3; last full paragraph in column 3; fourth full paragraph in column 4; and last paragraph in column 6. The polysaccharide composition is sterile and comprises a pharmaceutically acceptable carrier. See first full paragraph in column 24. The PS/A composition is formulated as a vaccine, or a pharmaceutical or therapeutic composition comprising a pharmaceutically acceptable carrier. See third full paragraph in column 3; and second, fourth and fifth full paragraphs in column 23. The PS/A polymers are conjugated to carrier compounds such as peptide, protein or other polysaccharide polymer carriers either directly or via a linker. See second full paragraph in column 14.

Claims 1, 2, 4-6, 8-25, 42 and 86-98 are anticipated by Pier *et al.* ('828).

Relevant Prior Art

22) The prior art made of record and not currently relied upon in any of the rejections is considered pertinent to Applicants' disclosure:

- Maira-Litran *et al.* (*In*: *Abstracts of the General Meeting of the American Society for Microbiology*, Orlando, Florida, pages 283-284, #D-42, May 20-24, 2001) taught an isolated staphylococcal PIA polysaccharide, poly-N-acetyl-beta-1-6 glucosamine, that is chemically derived such that it lacks detectable succinate and an isolated PNSG that is chemically derived such that it lacks any acetate. See abstract.

Remarks

23) Claims 1, 2, 4-25, 42 and 86-98 stand rejected.

24) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. The Fax number for submission of amendments, responses and/or papers is (571) 273-8300, which receives transmissions 24 hours a day and 7 days a week.

25) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.Mov. Should you have questions on access to the Private PAA

system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (in USA or CANADA) or 571-272-1000.

26) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Robert Mondesi, can be reached on (571) 272-0956.

/S. Devi/
Primary Examiner
AU 1645

March, 2009